

**OBJECTIVES:** Diabetes has been increasing worldwide and the treatment of type 2 diabetes is based on lifestyle modification and pharmacological therapy. Appropriate self-care practices including lifestyle modifications and medication compliance are critical to satisfactory control and management of diabetes and to prevent from comorbidities. The objective of this study was to assess current treatment patterns, treatment compliance and reasons for noncompliance for patients with type 2 diabetes in Pakistan. **METHODS:** A cross-sectional study was conducted to collect data through structured interviews based on pre-tested questionnaire. Total 211 patients including 46% males and 54% females from the ages 25 and over were randomly selected for the study from a population of patients attending 5 primary care diabetes centers throughout Karachi. Information was collected on socio-demographic characteristics, diabetes duration and compliance to physician's advice. **RESULTS:** Overall, median age for male subjects was 53 years, significantly older ( $p=0.008$ ) than females (46 years). The mean duration of diabetes among respondents was  $9.2\pm 3.8$  years. Of the total, majority of patients were treated with oral medication (61%). Only 27% reported full compliance as per physician's advice for timely medication, routine exercise, timely lab investigation and follow up for next visit. About 45% of the subjects were taking medication for diabetes related complications. Lack of financial resources, knowledge and supportive services and fear of needle were the main reasons for noncompliance. We also found that people with low literacy levels were less likely to manage their condition effectively compared to people with higher educational level ( $p<0.001$ ). **CONCLUSIONS:** To manage the diabetes both physicians and patients should attempt to improve compliance, which could lead to better disease management. Based on the findings, a public health intervention and information campaign is needed to change behaviours of persons with diabetes. Further, physicians can also educate patients by identifying potential risks of non-compliance and educate them accordingly.

## PDB44

#### A NOVEL APPROACH FOR NON-ADHERENCE MEASUREMENT BASED ON PRESCRIPTION DATA: THE EXAMPLE OF ORAL DIABETICS IN THE THERAPY OF TYPE-2 DIABETES MELLITUS PATIENTS

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**OBJECTIVES:** To quantify the influence of methodological assumptions/parameters on the results of prescription-based NA analysis based on 3-years prescription data (German Statutory Health Insurance Fund) covering 241,537 T2DM patients. **METHODS:** With the help of MPRs in an interval-based approach, a NA-base scenario for 25 anti-diabetic active ingredients was calculated for each patient. In a scenario analysis, the quantitative influence of all in all 9 parameters on the MPR level was derived. The most important parameter concerned the definition of an ideal prescription profile ("100%-adherer"). Assumptions simplifying the real prescription behaviour did not allow to accurately reflect the variety of medications and the clinical need to change medications. Therefore, a total of eight clinically meaningful prescription profiles were derived assigning patients exclusively by the use of self-developed algorithms. For each patient a MPR estimated by standard methodology (base case) was compared with the MPR based on our novel approach. **RESULTS:** In the base case, the average MPR resulting from the analysed active ingredient combinations was 80.76%. A total of 62.85% of patients had an MPR<80%. According to the novel prescription profiles, patients were distributed as follows: 59.9% Mono-medication, 12.9% Single-Drug Switcher, 11.3% Single-Drug Add-on, 2.0% Multiple-Drug Add-on, 5.0% Polytherapy consistent, 2.5% Polytherapy Add-on, 3.5% Polytherapy Drop-off, and 1.3% Polytherapy Switcher. A total of 1.6% of the patients could not unequivocally be assigned to one of the categories. Comparing a base-case MPR analysis with our novel approach resulted in MPR deviations in specific patient groups of up to 27.4 percentage points. **CONCLUSIONS:** Probably the biggest challenge in NA analysis based on prescription data is to differentiate between physician-induced and patient-induced medication changes. The first should be reflected in the adequate profile of an NA analysis and should not be misinterpreted as NA itself. The methodology described presents a powerful alternative for defining clinically meaningful prescription patterns.

## PDB45

#### THE PATIENT REPORTED EXPERIENCE OF LIVING WITH DIABETIC PERIPHERAL NEUROPATHIC PAIN (DPNP)

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**OBJECTIVES:** The burden of diabetic peripheral neuropathic pain (DPNP) on patients' lives is poorly understood and insufficiently measured with current instruments. Proper assessment of DPNP impact on patients' lives is critical to accurately determine treatment efficacy. **METHODS:** 45 blinded, semi-structured telephone interviews were conducted to assess the impact of DPNP on functioning and patient well-being enrolled in a randomized, double-blind, placebo-controlled study. Interviews were taped, transcribed, coded, and analyzed according to grounded theory principles. **RESULTS:** Patients were 31% female, 53% white and the average age was 56 years. Two major domains of burden were identified: physical functioning and daily life. Physical functioning was affected in 36 (80%) patients whose DPNP led to difficulty in walking, 33 (73%) reported low energy levels, and 32 (71%) noted a diminished ability to exercise. Twenty-five (55%) patients reported difficulties with bending, 22 (49%) difficulty standing, 20 (44%) reduced ease of movement, 19 (42%) had problems with balance and 16 (36%) in climbing stairs. DPNP affected sleep in 37 (82%) patients who reported awakening in the night, 28 (62%) had difficulty falling asleep, 16 (36%) couldn't fall back asleep once awakened; and 36 (80%)

patients rarely felt rested during the day. Daily life was affected in 34 (76%) patients leading to reduced productivity, 30 (67%) reported that DPNP reduced their enjoyment of life, and 26 (58%) found that DPNP limited their recreational activities. Twenty-four (53%) of patients had a reduced ability to focus on tasks due to pain, 22 (49%) reported that DPNP limited their ability to work, 20 (44%) experienced difficulty in accomplishing routine household chores, and 17 (38%) had reduced independence. **CONCLUSIONS:** DPNP causes significant burden on patient's physical functioning and daily life. PRO measures used to determine treatment efficacy should assess these impacts to accurately reflect the patient's perspective.

## PDB46

#### DEVELOPMENT OF THE DIABETIC PERIPHERAL NEUROPATHIC PAIN IMPACT MEASURE: A PATIENT-REPORTED OUTCOME MEASURE OF THE IMPACT OF DPNP ON FUNCTIONING

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**OBJECTIVES:** Diabetic Peripheral Neuropathic Pain (DPNP) is a poorly understood complication of diabetes that has serious consequences for patients' physical functioning and daily activities. A well-developed patient-reported outcome (PRO) measure that can assess the impact of DPNP on function and that is sensitive to change would facilitate research important to patients. The purpose of the study was to develop a measure of key impacts important to patients with DPNP. **METHODS:** Diabetic Peripheral Neuropathic Pain (DPNP) is a poorly understood complication of diabetes that has serious consequences for patients' physical functioning and daily activities. A well-developed patient-reported outcome (PRO) measure that can assess the impact of DPNP on function and that is sensitive to change would facilitate research important to patients. The purpose of the study was to develop a measure of key impacts important to patients with DPNP. **RESULTS:** Saturation of concepts was reached after 3 focus groups and telephone interviews with a total of 25 DPNP patients (demographics: average age 52 years old, 68% male, 60% White). The average duration of DPNP was 5 years (range 1-20 years) and the average self-reported pain score (scale 0-10) was 6.9 (range 4-10). The theoretical framework described two domains of impact: Physical Functioning and Daily Functioning. Based on the results of the cognitive debriefing a 27-item, validation ready version of the measure with 4 domains (Physical Functioning-Sleep, Physical Functioning-Mobility, Daily Functioning- Daily Activities and Daily Functioning-Relationships) was generated. **CONCLUSIONS:** The Diabetic Peripheral Neuropathic Pain Impact Measure is believed to accurately capture relevant DPNP patients' experiences as it relates to their ability to function. Data generated from the measure should assist clinicians in assessing key impacts in patients with DPNP, facilitate development of targeted treatments and provide a meaningful measurement of treatment effect.

## PDB47

#### NATIONAL IMPACT OF HEALTH CARE ACCESS ON HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH DIABETES IN THE UNITED STATES

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**OBJECTIVES:** Lack of access to healthcare for patients with diabetes has been associated with lower self-reported health-related quality of life (HRQOL), which may lead to significant economic burden. The objective of the study was to determine the impact of healthcare access on HRQOL of patients with diabetes. **METHODS:** The 2009 Behavioral Risk Factor Surveillance System (BRFSS), a national health telephone survey administered by the Centers for Disease Control and Prevention (CDC), was analyzed. It included questions on patient demographics and health-related perceptions, conditions, and behaviors. HRQOL was defined as the number of unhealthy days, a sum of physical and mental unhealthy days in the past one month. Healthcare access was defined by whether the patient had healthcare coverage, had a healthcare professional or could not see a doctor because of cost. Descriptive analysis included means, standard errors and relevant T-tests. Poisson regression was performed to measure the impact of healthcare access variables, age, race, gender, marital status and median household income on unhealthy days. **RESULTS:** In 2009, from 5.2 million diabetic patients, 0.7 million (14%) did not have healthcare coverage, 0.48 million (9%) did not have healthcare professional and 1.54 million (30%) could not see a doctor due to cost. The average number of unhealthy days in a month, for diabetic patients with healthcare coverage was lower than those without (22 days versus 23 days,  $p\text{-value}<0.01$ ); for those who could see a doctor due to cost was lower than those who could not (22 days versus 24 days,  $p<0.01$ ); was the same for those with or without a healthcare professional. Regression results showed, not having healthcare coverage and healthcare professional, each significantly ( $p\text{-value}<0.01$ ) increased an excess unhealthy day in diabetic patients. **CONCLUSIONS:** Lack of healthcare access negatively impacts HRQOL. Measures are needed to ensure adequate healthcare access in diabetic patients.

## PDB48

#### DO WE KNOW WHAT ARE THEY TRADING OFF? - A FEASIBILITY STUDY TO MEASURE QUALITY OF LIFE IN TAIWANESE TYPE-2 DIABETES OUTPATIENTS BY TIME-TRADE-OFF METHOD

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**OBJECTIVES:** To assess the quality of life (QoL) of Taiwanese type 2 diabetes patients, we have conducted feasibility studies applying different QoL utility scores. This study aims to explore the adaptation and feasibility of time-trade-off (TTO) method for measuring QoL in Taiwanese diabetic outpatients. **METHODS:** This cross-sectional study was conducted from June to December 2010 at nephrology